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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,406	06/08/2001	Jo Handelsman	AVI-001.03	8083

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,406

Applicant(s)

HANDELSMAN ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-30, 41 and 46-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 8-30, 41 and 46-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 2-6, 8-30, 41 and 46-48 are pending in the present application.

Response to Amendment

Claim 2 stands rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement.

Claims 2-30 stand rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for producing host cells expressing genomic DNA from uncultivated microorganisms, does not reasonably provide enablement for detecting a compound without prior knowledge of that compound or the nature of that compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The rejection of claims 2, 8-11, 13, 15-24 under 35 U.S.C. 102(e) as being anticipated by Short et al (Short et al US 6,057, 103) has been withdrawn in view of Applicant's amendments.

The rejection of claims 2-8, 10, 13-22, 24-29, 30, 41-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Thompson et al (Thompson et al US 5,824,485) has been withdrawn in view of Applicant's amendments.

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The rejection of claims 2, 10, 11, 12 and 14 under 35 U.S.C. 103(a) as being unpatentable over Short et al in view of Fuerst et al (Frobisher & Fuerst Microbiology Ch.2, pages 14-22, 1983) and Stein et al (J. Bacteriology, Vol. 178, pages 591-599, 1996) has been withdrawn in view of Applicant's amendments.

Response to Arguments

Claims 2 and 33 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicant argues that:

Claim 2 as amended is directed to a method for "detecting" a compound produced by a biosynthetic pathway. . . . A compound produced by the host cells as a result of expression of the open reading frame sequence is then detected by various means. . . . Note that as amended, Claim 2 does not require that the chemical structure or "identity" of the compound be discovered or known. See Remarks filed 12/28/04, pages 12-13.

Applicant's arguments are noted however not found persuasive. The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . . [emphasis added]." A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

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Applicant has based his argument that the method does not require the identification of the compound claimed in the method. The question presented by the instant rejection under the written description requirement of 35 U.S.C. 112, first paragraph is whether Applicant had possession of such a broad genus of "compounds." Amending the claims to recite the term detection does not obviate the issue that one of skill in the art would not reasonably conclude that Applicant was in possession of the broad genus claimed.

The specification describes and the method claims the isolation of genomic DNA from environmental samples containing uncultivated microorganisms, construction of expression vectors containing the genomic DNA from various microorganisms, transformation of a host cell with the vectors and maintenance of the host cells under conditions to express the DNA. The specification fails to recite a nexus between the genomic DNA and the compounds and also fails to describe any common features or properties of these compounds as to indicate that Applicant was in possession of the genus. Absent such evidence in clear, concise and exact terms, one of skill in the art would not reasonably conclude that Applicant was in possession of the invention claimed.

Claim 2-30, 32 and 33 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing host cells expressing genomic DNA from uncultivated microorganisms, does not reasonably provide enablement for detecting a compound without prior knowledge of that compound or the nature of that compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to use the invention commensurate in scope with these claims. This rejection is maintained for the reasons already of record and those set forth below.

Applicant argues that one does not need any prior knowledge of a compound or the nature of that compound in order to detect its presence and that the claims do not require that the chemical structure of the compound be identified or isolated. In support of this position Applicant discusses the work of Pierre and Marie Curie who detected radium before they were able to isolate a sufficient quantity to characterize it. Although the historical discussion is appreciated and noted, it is not analogous to the claims at issue because radium clearly was emitting radiation that was detected by the methods of the Curie's. However, in the present case, Applicant is trying to make a very fine distinction between "identification" and "detection." It is the examiner's position that to detect the compounds some sort of identification of that compound is required. Applicant in their arguments lists the many assays that may be used to detect a compound. The very act of measuring the differences in glycosylation patterns, for example, in the modified host requires discrimination between proteins. Moreover, changes in glycosylation, transcription, translation in a cell may be a result of damage in transforming the host rather than the detection of any supposed "compound." Without some knowledge as to what Applicant is looking for in that compound, *i.e.* identification, the assay to be used and results may change. Additionally, with regard to the Curies, in their work they were discriminating between radium and other compounds by the radiation emitted by the compound, and in this way they did identify the element. Therefore, the full scope of the claim is not enabled.

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New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 2-6, 8-30, 41 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to include the negative limitation, “without an intervening step of isolating or culturing cells from the source.” The examiner has failed to find support for this limitation in the specification. The examiner found a statement on page 1 of the specification discussing a paper by Torvisk et al. that a study was conducted without culturing microorganisms to determine biodiversity in a sample. On page 6 of the specification, Applicant states: “by eliminating initial culturing steps in the sub-cloning process, one of the salient features of the subject method is that it can be carried out in a manner which provides a relatively unbiased approach to cloning components of a biosynthetic pathway.” The specification appears to provide support for eliminating a culturing step, however, not eliminating an isolating step. Therefore, the written description requirement has not been met.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Examiner
Art Unit 1636


JAMES KETTER
PRIMARY EXAMINER